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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/567,754

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Akinori Arimura

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EXAMINER

RICCI, CRAIG D

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

02/17/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/567,754	Applicant(s) ARIMURA, AKINORI	
	Examiner CRAIG RICCI	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/20/2008</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. The amendments filed 11/03/2008 were entered.
2. The rejection of claim 7 under 35 USC 112 second paragraph has been withdrawn in view of Applicant's cancellation of the claim.
3. The rejection of claim 8 under 35 USC 112 second paragraph has been withdrawn in view of Applicant's amendment of the claim.
4. The rejection of claim 7 under 35 USC 101 has been withdrawn in view of Applicant's cancellation of the claim.
5. The rejection of claim 8 under 35 USC 102(b) has been withdrawn in view of Applicant's amendment of the claim.

Response to Arguments



6. Applicants' arguments, filed 11/03/2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

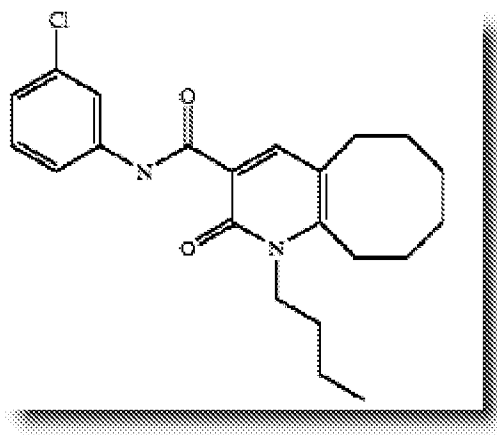
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. **Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Tada et al* (US 6,977,266) in view of *Berdyshev et al* (Life Sci 63(8):PL125-129, 1998), both of which were cited in a previous action.**

9. The following rejection is necessitated by amendment.

10. Amended claim 8 is drawn to methods of treating a mammal to alleviate the pathological effects of an inflammatory cell infiltration in the respiratory tract, a hyperirritability in the respiratory tract, a muciparous, or a bronchoconstrictive action wherein the method comprises administering to a mammal in need thereof, a cannabinoid receptor antagonist represented by formula (II) in a pharmaceutically effective amount.

11. *Tada et al* disclose compounds represented by formula (II). For example, *Tada*



et al teach the following compound

(Column 334,

Compound No. B-008) which encompasses a compound of formula (II) wherein R⁵ is Y¹-Y²-Y³-R^a and Y¹ is a direct bond, Y² is -C(=O)-NR^b, R^b is H, Y³ is a direct bond, and R^a is an optionally substituted carboxylic group; R⁶ is H; R⁷ and R⁸ form an 8

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membered ring; and R⁹ is alkyl. Additionally, *Tada et al* teach that the compounds of the invention are CB2 agonists (Abstract).

12. Furthermore, *Tada et al* teach “a method... which comprises administering to the mammal a pharmaceutically effective amount” of the compound (Column 363, Lines 49-51) and that “the compound of the present invention can be used for treating or preventing diseases related to the cannabinoid type 2 receptor” (Column 60, Lines 55-57). More specifically, *Tada et al* teach that “the present compounds can be used as anti-inflammatory agents, anti-allergenic agents, analgesic agents, immunodeficiency treating agents, autoimmune disease treating agents, chronic rheumatoid arthritis treating agents, multiple sclerosis treating agents, encephaloma treating agents, glaucoma treating agents or the like” (Column 61, Lines 3-14). However, *Tada et al* do not specifically teach the use of the compound for treating the respiratory conditions recited by instant claim 8.

13. *Berdyshev et al* teach the use of cannabinoid type 2 receptor agonists to treat the pathological effects encompassed by instant claim 8. Specifically, *Berdyshev et al* tested the effects of cannabinoid receptor agonists on bronchopulmonary inflammation in mice and found that the CB2 agonist, WIN 55,212,2, reduced the recruitment of neutrophils (inflammatory cells) and downmodulated bronchopulmonary inflammation (a pathological effect of an inflammatory cell infiltration in the respiratory tract and a hyperirritability of the respiratory tract) (Page PL-128).

14. Since *Tada et al* teach the use of the instant compound represented by the formula (II), which is a CB2 agonist, in the treatment of diseases, and since *Berdyshev*

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et al teach that CB2 agonists “inhibited LPS-induced pulmonary inflammation and suggest that this effect could be at least in part mediated by the cannabinoid CB2 receptor” (abstract), it would have been *prima facie* obvious to a person of ordinary skill in the art to use the CB2 agonist as taught by *Tada et al* to treat an inflammatory cell infiltration or respiratory hyperirritability as taught by *Berdyshev et al*. Accordingly, claim 8 is rejected as *prima facie* obvious.

15. Applicant traverses this rejection. Citing *Szarka et al*, Applicant argues that “intranasal instillation of LPS into BALB/c mice causes acute pulmonary damage, due to neutrophil infiltration and sepsis... [and] this LPS i.n. instillation model may help continue the study of pulmonary edema, ARDS, sepsis, and toxic shock, with the understanding of therapeutic development or cytokine effectiveness” (Applicant Argument, Page 6). Accordingly, Applicant concludes that *Berdyshev et al* (who teach that CB2 agonists significantly reduce LPS-induced neutrophil recruitment (Page PL-128, Paragraph 1) and inhibit pulmonary inflammation (Abstract)) “does not relate to an inflammatory cell infiltration in the respiratory tract, a hyperirritability in the respiratory tract, a muciparous, or a bronchoconstrictive action” (Applicant Argument, Page 7). Although unclear, Applicant seemingly argues that *Berdyshev et al* does not relate to an inflammatory cell infiltration in the respiratory tract because *Szarka et al* disclose that the LPS model (employed by *Berdyshev et al*) may help continue the study of pulmonary edema, ARDs, etc, but *Szarka et al* do not indicate that the LPS model can be used to study an inflammatory cell infiltration in the respiratory tract. This argument is not found persuasive. As previously discussed, *Berdyshev et al* explicitly teach that

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“inhalation of LPS induced a clear inflammatory response in the lung of mice which was characterized by massive neutrophil recruitment and release of TNF- α in BALF” all of which were significantly inhibited by the CB2 agonist, WIN 55,212-2 (Page PL-128, Paragraph 1). Accordingly, *Berdyshev et al* teach that the CB2 agonist, WIN 55,212-2, treats the pathological effect (inflammation) of an inflammatory cell (neutrophil) infiltration in the respiratory tract (lung) as recited by instant claim 8. Accordingly, it would have been *prima facie* obvious to a person of ordinary skill in the art to use the CB2 agonist as taught by *Tada et al* to treat the pathological effects of an inflammatory cell infiltration in the respiratory tract with a high expectation of success.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRAIG RICCI whose telephone number is (571) 270-5864. The examiner can normally be reached on Monday through Thursday, and every other Friday, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CRAIG RICCI/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614